9. TEXT.

SUBCHAPTER A. GENERAL PROVISIONS

§12.1. Statutory Basis. This chapter implements the Insurance Code Chapter 4202 as of September 1, 2013 [~~2009~~].

§12.2. Severability Clause. If a court of competent jurisdiction holds that any provision of this chapter or its application to any person or circumstance is invalid for any reason, the invalidity does not affect other provisions or applications of this chapter that can be given effect without the invalid provision or application, and to this end the provisions of this chapter are severable.

§12.3. Effect of Chapter. The sections in this chapter are prescribed to govern the performance of appropriate statutory and regulatory functions and are not to be construed as limitations upon the exercise of statutory authority by the Commissioner of Insurance.

§12.4. Applicability.

(a) All independent review organizations performing independent reviews of adverse determinations made by utilization review agents, health insurance carriers, health maintenance organizations, and managed care entities, must comply with this chapter. Independent review organizations performing independent reviews of adverse determinations made by certified workers' compensation health care networks and workers' compensation insurance carriers must comply with this chapter, subject to §12.6 of this subchapter (relating to Independent Review of Adverse Determinations of

Health Care Provided Pursuant to the Labor Code Title 5, or the Insurance Code Chapter 1305).

(b) Except as otherwise provided, this chapter is applicable to all requests for independent review filed with the department on or after December 26, 2010. All independent reviews filed with the department prior to December 26, 2010, shall be subject to the rules in effect at the time the independent review was filed with the department.

§12.5. Definitions. The following words and terms, when used in this chapter, shall have the following meanings unless the context clearly indicates otherwise.

(1) Adverse determination--A determination by a utilization review agent made on behalf of any payor that the health care services provided or proposed to be provided to a patient are not medically necessary or appropriate, or are experimental or investigational.

(2) Affiliate--A person who directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with the person specified.

(3) Best evidence--Evidence based on:

(A) randomized clinical trials;

(B) if randomized clinical trials are not available, cohort studies or case-control studies;

(C) if subparagraphs (A) and (B) are not available, case-series; or

(D) if subparagraphs (A), (B) and (C) are not available, expert opinion.

(4) Biographical Affidavit. National Association of Insurance Commissioners biographical affidavit to be used as an attachment to the IRO application.

(5) Case-control studies--A retrospective evaluation of two groups of patients with different outcomes to determine which specific interventions the patients received.

(6) [~~(5)~~] Case-series--An evaluation of a series of patients with a particular outcome, without the use of a control group.

(7) [~~(6)~~] Cohort studies--A prospective evaluation of two groups of patients with only one group of patients receiving a specific intervention(s).

(8) [~~(7)~~] Commissioner--The Commissioner of Insurance.

(9) [~~(8)~~] Department--Texas Department of Insurance.

(10) [~~(9)~~] Dentist--A licensed doctor of dentistry holding either a D.D.S. or a D.M.D. degree.

(11) [~~(10)~~] Evidence-based medicine--The use of current best quality scientific and medical evidence formulated from credible scientific studies, including peer-reviewed medical literature and other current scientifically based texts, and treatment and practice guidelines in making decisions about the care of individual patients.

(12) [~~(11)~~] Evidence-based standards--The conscientious, explicit, and judicious use of evidence-based medicine and the current best evidence based on the overall systematic review of the research in making decisions about the care of individual patients.

(13) [~~(12)~~] Experimental or investigational--A service or device for which there is early, developing scientific or clinical evidence demonstrating the potential efficacy of the treatment, service, or device but that is not yet broadly accepted as the prevailing standard of care.

(14) [~~(13)~~] Expert opinion--A belief or an interpretation by specialists with experience in a specific area about the scientific evidence pertaining to a particular service, intervention, or therapy.

(15) [~~(14)~~] Health benefit plan--A plan of benefits that defines the coverage provisions for health care offered or provided by any organization, public or private, other than health insurance.

(16) [~~(15)~~] Health care provider or provider--A person, corporation, facility, or institution that is:

(A) licensed by a state to provide or otherwise lawfully providing health care services; and

(B) eligible for independent reimbursement for those services.

(17) [~~(16)~~] Health insurance policy--An insurance policy, including a policy written by a corporation subject to the Insurance Code Chapter 842, that provides coverage for medical or surgical expenses incurred as a result of accident or sickness.

(18) [~~(17)~~] Independent review--A system for final administrative review by a designated independent review organization of an adverse determination regarding the medical necessity and appropriateness or the experimental or investigational nature of health care services.

(19) [~~(18)~~] Independent review organization or IRO--An entity that is certified by the commissioner to conduct independent review under the authority of the Insurance Code Chapter 4202. Such entity must have the capacity for independent review of all specialty classifications and subspecialties thereof contained in the two tiered structure of specialty classifications set forth in §12.402 of this chapter (relating to Classification of Specialty).

(20) [~~(19)~~] Independent review plan--The review criteria and review procedures of an independent review organization.

(21) IRO application--Form for application for, renewal of, and reporting a material change to a certification as an IRO in this state.

(22) [~~(20)~~] Legal holiday--A holiday:

(A) as provided in the Government Code §662.003(a), including New Year's Day; Martin Luther King, Jr. Day; Presidents' Day; Memorial Day; Independence Day; Labor Day; Veterans Day; Thanksgiving Day; and Christmas Day; and

(B) as provided in §102.3(b) of this title, (relating to Computation of Time), the Friday after Thanksgiving Day; December 24th; and December 26th.

(23) [~~(21)~~] Life-threatening condition--A disease or condition for which the likelihood of death is probable unless the course of the disease or condition is interrupted.

(24) [~~(22)~~] Medical and scientific evidence--Evidence found in the following sources:

(A) peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff;

(B) peer-reviewed medical literature, including literature relating to therapies reviewed and approved by a qualified institutional review board, biomedical compendia and other medical literature that meet the criteria of the National Institute of Health's National Library of Medicine for indexing in Index Medicus (Medline) and Elsevier Science Ltd. for indexing in Excerpt--Medicus (EMBASE);

(C) medical journals recognized by the Secretary of Health and Human Services, pursuant to Section 1861(t)(2) of the federal Social Security Act;

(D) the following standard reference compendia:

(i) the American Hospital Formulary Service Drug Information;

(ii) Drug Facts and Comparisons, current edition as published by Lippincott Williams & Wilkins;

(iii) the American Dental Association Accepted Dental Therapeutics; and

(iv) the United States Pharmacopoeia--Drug Information;

(E) findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes including:

(i) the Federal Agency for Healthcare Research and Quality;

(ii) the National Institutes of Health;

(iii) the National Cancer Institute;

(iv) the National Academy of Sciences;

(v) the Centers for Medicare & Medicaid Services;

(vi) the federal Food and Drug Administration; and

(vii) any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health care services;

(F) peer-reviewed abstracts accepted for presentation at major medical association meetings;

(G) for independent review of adverse determinations of health care provided pursuant to the Labor Code Title 5, the treatment guidelines, treatment protocols, and pharmacy closed formulary as provided in applicable orders issued or rules adopted by the TDI-DWC pursuant to the Labor Code §408.028 and §413.011, including Chapter 134 of this title (relating to Benefits--Guidelines for Medical Services, Charges, and Payments) and Chapter 137 of this title (relating to Disability Management); or

(H) any other medical or scientific evidence that is comparable to the sources listed in subparagraphs (A) - (F) of this paragraph.

(25) [~~(23)~~] Nurse--A registered or professional nurse, a licensed vocational nurse, or a licensed practical nurse.

(26) [~~(24)~~] Patient--The enrollee or an eligible dependent of the enrollee under a health benefit plan or health insurance policy, or an injured employee entitled to receive workers' compensation benefits pursuant to the Labor Code Title 5.

(27) [~~(25)~~] Payor--

(A) an insurer that writes health insurance policies;

(B) a preferred provider organization, health maintenance organization, or self-insurance plan; or

(C) any other person or entity that provides, offers to provide, or administers hospital, outpatient, medical, or other health benefits, including workers' compensation benefits as provided under the Insurance Code §4201.054, to persons treated by a health care provider in this state under a policy, plan, or contract.

(28) [~~(26)~~] Person--An individual, corporation, partnership, association, joint stock company, trust, unincorporated organization, any similar entity, or any combination of the foregoing acting in concert.

(29) Physical Address--Location where the activities and computer systems described in the Insurance Code §4202.002(f) are maintained, performed, and located and where personnel are reasonably available by telephone at least 40 hours per week during normal business hours in both Central and Mountain time zones, to discuss or respond to requests for independent review.

(30) [~~(27)~~] Physician--A licensed doctor of medicine or a doctor of osteopathy.

(31) [~~(28)~~] Primary office--The place where~~, based upon the totality of the business activities related to independent review performed under this chapter,~~ an independent review organization[~~'s~~] maintains its physical address and its books and records pertaining to independent reviews assigned by the Department are maintained and accessible [~~stored~~].

(32) [~~(29)~~] Provider of record--The physician or other health care provider that has primary responsibility for the care, treatment, and services rendered or requested on behalf of the patient; or the physician or health care provider that has rendered or has been requested to provide the care, treatment, or services to the patient. This definition includes any health care facility where treatment is rendered on an inpatient or outpatient basis.

(33) [~~(30)~~] Randomized clinical trial--A controlled, prospective study of patients that have been randomized into an experimental group and a control group at the beginning of the study with only the experimental group of patients receiving a specific intervention, which includes study of the groups for variables and anticipated outcomes over time.

(34) [~~(31)~~] Review criteria--The written policies, medical protocols, previous decisions and/or guidelines used by the independent review organization to make decisions about the medical necessity or appropriateness of a treatment, procedure, or service or the experimental or investigational nature of a treatment, procedure, or service.

(35) [~~(32)~~] TDI-DWC--The Texas Department of Insurance, Division of Workers' Compensation.

(36) [~~(33)~~] Utilization review agent--A person holding a certificate under the Insurance Code Chapter 4201.

(37) [~~(34)~~] Working day--A weekday that is not a legal holiday.

§12.6. Independent Review of Adverse Determinations of Health Care Provided Pursuant to the Labor Code Title 5, or the Insurance Code Chapter 1305.

(a) Review of the medical necessity or appropriateness of a health care service provided under the Labor Code Chapter 408 or Chapter 413 shall be conducted under this chapter in the same manner as reviews of utilization review decisions by health maintenance organizations.

(b) Notwithstanding subsection (a) of this section, for independent review of adverse determinations of health care provided pursuant to the Labor Code Title 5 or the Insurance Code Chapter 1305:

(1) independent review organizations and personnel conducting independent review must comply with the Labor Code Title 5 and applicable TDI-DWC rules;

(2) in the event of a conflict between this chapter and the Labor Code, the Labor Code controls; and

(3) in the event of a conflict between this chapter and TDI-DWC rules, TDI-DWC rules control.

SUBCHAPTER B. CERTIFICATION OF REGISTRATION FOR INDEPENDENT REVIEW

§12.101. Certification of Registration for Independent Review [~~Where to File Application~~]. An application for a certificate of registration and for renewal of a certificate of registration as an independent review organization and application for a certificate of registration or renewal fee must be filed with the Texas Department of Insurance at the following address: Texas Department of Insurance, Mail Code 103-6A, P.O. Box 149104, Austin, Texas 78714-9104.

§12.102. Independent Review Organization (IRO) Application Form [~~Application and Renewal of Certificate of Registration Form; How to Obtain Forms~~].

(a) The commissioner adopts by reference the [~~Form No. LHL006 (~~] IRO Application Form [~~) to be used~~] for application, [~~for a certificate of registration and for~~] renewal of, and reporting a material change to a certificate of registration as an independent review organization in this state.

(b) The commissioner adopts by reference NAIC Form Number 11 [~~Form No. FIN311~~] (Biographical Affidavit) to be used as an attachment to the [~~Form No. LHL006 (~~] IRO Application Form [~~), the application for the certificate of registration and for renewal of a certificate of registration as an independent review organization in this state~~].

(c) The forms are available at http://www.tdi.texas.gov/forms [~~http://www.tdi.state.tx.us/forms~~]. The forms may also be obtained from the Texas Department of Insurance, Mail Code 103-6A, 333 Guadalupe, P.O. Box 149104, Austin, Texas 78714-9104.

§12.103. Information Required in Original Application for Certificate of Registration [~~and Renewal Form~~]. The IRO Application Form [~~No. LHL006~~] requires information necessary for the commissioner to properly determine whether an applicant is qualified to be certified as an independent review organization pursuant to the Insurance Code §4202.004, including:

(1) a summary of the independent review plan that meets the requirements of §12.201 of this chapter (relating to Independent Review Plan) and must include:

(A) a summary description of review criteria and review procedures to be used to determine medical necessity or appropriateness of health care;

(B) a summary description of review criteria and review procedures to be used to determine the experimental or investigational nature of health care;

(C) a certification signed by the IRO's medical director [~~an authorized representative~~] that such review criteria and review procedures to be applied in review determinations are established with input from appropriate health care providers and approved by physicians in accordance with §12.201(3) of this chapter; and

(D) procedures ensuring that the information regarding the reviewing physicians and providers is updated in accordance with §12.110(a) [~~§12.105(d)~~] of this subchapter (relating to Regulatory Requirements Subsequent to Certification [~~Revisions During Review Process) and §12.108(e) of this subchapter (relating to Renewal of Certificate of Registration~~]) to ensure the independence of each health care provider or physician making review determinations.

(2) copies of policies and procedures which ensure that all applicable state and federal laws to protect the confidentiality of medical records and personal information are followed. These procedures must comply with §12.208 of this chapter (relating to Confidentiality);

(3) a certification signed by an officer, director, or owner of the IRO [~~authorized representative~~] that the independent review organization will comply with the Insurance Code Chapter 4202; [~~.~~]

(4) a description of personnel and credentialing, and a completed profile for each physician and provider, both as described in §12.202 of this chapter (relating to Personnel and Credentialing), including:

(A) the procedure used by the applicant to verify physician and provider credentials, including the computer processes, electronic databases, and records if any used; and

(B) the credentialing software used by the applicant for managing the processes, databases, and records described above if any used;

(5) a description of hours of operation and how the independent review organization may be contacted after hours, during weekends and holidays, as set forth in §12.207 of this chapter (relating to Independent Review Organization Telephone Access);

(6) a description of the applicant's use of communications, records, and computer processes to manage the independent review process;

(7) a description of and evidence of accreditation from a nationally recognized accrediting organization, if any, that imposes requirements for accreditation that are the same as, substantially similar to, or more stringent that the department's requirements for certification. Evidence of certification will be maintained in the department's file for the organization and the applicant may request expedited approval of the certification with evidence of accreditation from a nationally recognized accrediting organization.

(8) the organizational information, documents and all amendments, including:

(A) written evidence that the applicant is doing business in this state in accordance with the Business Organizations Code, which may include a letter from the Texas Secretary of State indicating the entity has filed the appropriate information to conduct business in this state [~~the bylaws, rules and regulations, or any similar document regulating the conduct of the internal affairs of the applicant with a notarized certification bearing the original signature of an officer or authorized representative of the applicant that they are true, accurate, and complete copies of the originals~~];

(B) for an applicant that is publicly held, the name of each stockholder or owner of more than five percent of any stock or options;

(C) a chart showing the internal organizational structure of the applicant's management and administrative staff; and

(D) a chart showing contractual arrangements of the applicant, including a description of the service or services that the person who contracts with the independent review organization performs for the independent review organization.

(9) [~~(7)~~] the name of any holder of bonds or notes of the applicant that exceed $100,000;

(10) [~~(8)~~] the name and type of business of each corporation or other organization that the applicant controls or is affiliated with and the nature and extent of the affiliation or control and a chart or list clearly identifying the relationships between the applicant and any affiliates;

(11) [~~(9)~~] biographical information about officers, directors, owners, shareholders, and executives, including information requested in NAIC Form Number

11 [~~No. FIN311~~] (Biographical Affidavit) as required in §12.102(b) of this subchapter (relating to Independent Review Organization (IRO) Application Form [~~Application and Renewal of Certificate of Registration Form; How to Obtain Forms~~]):

(A) the applicant must submit the name, biographical information, and, in compliance with §1.503 and §1.504 of this title (relating to Application of Fingerprint Requirement and Fingerprint Requirement), a complete set of fingerprints for each director, officer, and executive of the applicant, any entity listed under paragraph (10) [~~(8)~~] of this section, and a description of any relationship the named individual has which represents revenue equal to or greater than five percent of that individual's total annual revenue or which represents a holding or investment worth $100,000 or more in any of the following entities:

(i) a health benefit plan;

(ii) a health maintenance organization;

(iii) an insurer;

(iv) a utilization review agent;

(v) a nonprofit health corporation;

(vi) a payor;

(vii) a health care provider;

(viii) another independent review organization; or

(ix) a group representing any of the entities described by clauses (i) - (viii) of this subparagraph.

(B) the applicant must identify any relationship between the applicant and any affiliate or other organization in which an officer, director, or employee of the applicant holds a five percent or more interest;

(C) the applicant must submit a list of any currently outstanding loans or contracts to provide services between the applicant, [~~and any~~] affiliates, or any other person relating to any functions performed by or on behalf of the independent review organization;

(12) the applicant must submit documentation from the Office of theTexas Comptroller demonstrating the applicant's good standing and right to transact business in this state;

(13) [~~(10)~~] for an application for a certificate or renewal of registration as an independent review organization in this state made on or after XX/XX/XXXX [~~December 26, 2010~~], an attestation from an officer of the organization that:

(A) [~~evidence that~~] the applicant's primary office noted on the application is located and maintained at a physical address in this state. As a condition of being certified to conduct the business of independent review in this state, an independent review organization must locate and maintain its primary office at a physical address in this state;

(B) the primary office is equipped with a computer system computer system capable of:

(i) processing requests for independent review; and

(ii) accessing all electronic records related to the review and the independent review process;

(C) all records are maintained electronically and will be made available to the department on request;

(D) in the case of an office located in a residence, the working office is located in a room set aside for independent review business purposes and in a manner to ensure confidentiality; and

(E) medical records are maintained in accordance with §12.208 of this chapter (relating to Confidentiality).

(14) [~~(11)~~] the percentage of the applicant's revenues that are anticipated to be derived from independent reviews conducted; and

(15) [~~(12)~~] a disclosure of any enforcement actions related to the provision of medical care or conducting of medical reviews taken against a person subject to the fingerprint requirements under §1.503 and §1.504 of this title.

§12.104. Review of Original Application. The original application process is as follows:

(a) Original application process. Within 60 calendar days after receipt of a complete original application, the department will process the application and issue or deny a certification. The department will send a certificate to an entity that is granted certification. The applicant may waive the time limit described in this subsection.

(b) Omissions or deficiencies.

(1) The department will send the applicant written notice of any omissions or deficiencies in the application.

(2)The applicant must correct the omissions or deficiencies in the application within 15 working days of the date of department's latest notice of the omissions or deficiencies. The applicant may request additional time in writing in which

to make the revisions. In the request, the applicant must specifically set out the length of time requested, not to exceed 30 days, and must include sufficient detail for the commissioner or the commissioner's designee to determine whether good cause for such extension exists. The commissioner or the commissioner's designee may grant or deny any request for an extension of time at the discretion of the commissioner or the commissioner's designee.

(3) If the applicant fails to do make the corrections within the allotted time, the application will be closed as an incomplete application. The application fee is not refundable.

~~[(1) After review, the department shall certify the application, provide the applicant written notice of any omissions or deficiencies noted as a result of the review conducted pursuant to this section, or deny the application.~~

~~(2) The applicant must correct the omissions or deficiencies in the application within 30 days of the date of the department's notice of such omissions or deficiencies.~~

~~(3) The applicant may waive any of the time limits specified in this section, except as set forth in paragraph (2) of this section. The applicant may waive the time limit in paragraph (2) of this section only with the consent of the department.~~

~~(4) Department staff shall notify the applicant of any omission or deficiencies noted during its review and inform the applicant that the application will be denied, absent corrections. If the time required for the revisions will exceed 30 days, the applicant must request additional time within which to make the revisions. In the request, the applicant must specifically set out the length of time requested, not to~~

~~exceed 90 days, and must include sufficient detail for the commissioner or the commissioner's designee to determine whether good cause for such extension exists. The commissioner or the commissioner's designee may grant or deny any request for an extension of time at the discretion of the commissioner or the commissioner's designee. The department shall review all revisions and take action as provided in paragraph (1) of this section.~~]

(4) [~~(5)~~] The department shall maintain a charter file which shall contain the application, notices of omissions or deficiencies, responses, and any written materials generated by any person that were considered by the department in evaluating the application.

§12.105. Revisions During Review Process.

(a) Revisions during the review of the application must be either by submitted electronically as designated by the department or addressed to: Texas Department of Insurance, Mail Code 103-6A, 333 Guadalupe, P.O. Box 149104, Austin, Texas 78714-9104.

(b) [~~The applicant must submit an original plus one copy of any revised page required by the department pursuant to this subchapter. Each revision to the organizational document or bylaws must be accompanied by the notarized certification of an officer or authorized representative of the applicant that the item submitted is true, accurate, and complete, and, if the item is a copy, by a notarized certification that the copy is a true, accurate, and complete copy of the original.~~

~~(c)~~] If a page is to be revised, [~~all copies of~~] the revised page submitted by the applicant must contain the changed item or information "red-lined." [~~or otherwise clearly~~

~~designated. The original revised page required to be submitted under subsection (b) of this section shall be placed in the charter file maintained by the department.~~

~~(d) The independent review organization shall report any material changes in the information in the application required by §12.102 of this subchapter (relating to Application and Renewal of Certificate of Registration Form; How to Obtain Forms) or renewal form required by §12.108 of this subchapter (relating to Renewal of Certificate of Registration) not later than the 30th day before the date on which the change takes effect.~~

~~(e) Compliance with subsection (d) of this section is exempted in the event that a contracted specialist is unavailable for review, and subsequent immediate contracting with a new specialist is necessary to complete independent review within the timeframes set forth in this chapter.~~

~~(f) The independent review organization shall notify the department within 10 days of any contracts entered into pursuant to subsection (e) of this section, and shall include in such notification a complete explanation of the circumstances necessitating such contracts.~~]

§12.106. [~~Qualifying~~] Examinations.

(a) The commissioner or the commissioner's designee may conduct an on-site [~~qualifying~~] examination at the [~~of an~~] applicant's primary office as a requirement of applying for a certificate of registration [~~or renewing a certificate of registration as an independent review organization~~].

(b) The commissioner or the commissioner's designee may conduct an examination of an independent review organization as often as the commissioner or

commissioner's designee deems necessary to determine compliance with the Insurance Code Chapter 4202 and this chapter including upon renewal of the certificate of registration.

(c) The following documents, including but not limited to, [~~Documents that support the application for the certificate of registration or renewal of the certificate of registration~~] must be available for review during the [~~inspection at the time of such qualifying~~] examination at the primary office of the independent review organization located within this state:

(1) the information required in §12.103 of this subchapter (relating to Information required in Original Application for Certificate of Registration);

(2) credentialing files;

(3) case decisions files;

(4) list of personnel who are available at the IRO's primary office 40 hours a week during normal business hours in both time zones in this state;

(5) list of officers and board of directors;

(6) list of all contractual relationships between the IRO and any person or entities relating to the operation of the IRO;

(7) chart showing the internal organizational structure of the IRO's management and administrative staff;

(8) chart showing the contractual arrangements of the IRO; and

(9) any other documents related to the operation of the IRO.

(d) The owner and IRO staff (i.e., CEO, Medical Director, and operations staff) must be available at the IRO's primary office during the on-site examination to

address all questions regarding the IRO's operations, produce all documents, and demonstrate to the examiners the operations of the IRO.

§12.107. Withdrawal of an Original Application and Subsequent to Certification.

(a) Upon written notice to the department, an applicant may request withdrawal of an application from consideration by the department.

(b) Upon the department's receipt of a request to withdraw an application pursuant to this section, the application shall be withdrawn from consideration. Subsequent applications by the same applicant must be new submissions in their entirety.

§12.108. Renewal of Certificate of Registration.

(a) The commissioner shall designate biennially [~~annually~~] each organization that meets the standards as an independent review organization.

(b) An independent review organization must apply for renewal of its certificate of registration biennially [~~every year~~], not later than the anniversary date of the issuance of the registration. The [~~Form No. LHL006 (~~] IRO Application Form[~~)~~], adopted by reference in §12.102 of this subchapter (relating to Independent Review Organization (IRO) Application Form [~~and Renewal of Certificate of Registration Form; How To Obtain Forms~~]), must be used for this purpose. The IRO Application Form [~~No. LHL006~~] can be obtained from the website and from the address listed in §12.102 of this subchapter. The completed renewal form, [~~a summary of the current review criteria,~~] renewal fee, and a certification that no material changes exist that have not already been filed with the department must be submitted to the department at the address listed in §12.101 of this subchapter (relating to Certification of Registration for

Independent Review [~~Where To File Application~~]). [~~Material changes shall include changes relating to physicians or providers performing independent review.~~]

(c) An independent review organization may continue to operate under its certificate of registration after a completed renewal application form, application fee, and a summary of the current review criteria have been received by the department until the renewal is finally denied or issued by the department. However, independent reviews will not be assigned to an independent review organization during the 30 days prior to the anniversary date of the issuance of the independent review organization's certificate of registration unless a completed renewal application form and the application fee have been received by the department.

(d) If a completed renewal application form is [~~and a summary of the review criteria are~~] not received prior to the anniversary date of the year in which the certificate of registration must be renewed, the certificate of registration will automatically expire and the independent review organization must complete and submit a new application for certificate of registration.

(e) [~~The independent review organization shall report any material changes in the information required in Form No. LHL006, including changes relating to physicians and providers performing independent review, not later than the 30th day before the date on which the change takes effect.~~

~~(f) Compliance with subsection (e) of this section is exempted in the event that a contracted specialist is unavailable for review, and subsequent immediate contracting with a new specialist is necessary to complete independent review within the timeframes set forth in this chapter.~~

~~(g) The independent review organization shall notify the department within 10 days of any contracts entered into pursuant to subsection (f) of this section, and shall include in the notification a complete explanation of the circumstances necessitating such contracts.~~

~~(h)~~] Until the certificate of registration renewal application process is complete or the certificate of registration expires, an independent review organization must:

(1) continue to perform its duties pursuant to the Insurance Code Chapter 4202, the Labor Code, and department and TDI-DWC rules, including maintenance and retention of medical records and patient-specific information pursuant to §12.208 of this chapter (relating to Confidentiality); and

(2) in regard to reviews of the medical necessity of a health care service provided under the Labor Code Title 5 or Insurance Code Chapter 1305, make responses to requests for letters of clarification pursuant to §133.308 of this title (relating to MDR by Independent Review Organizations).

§12.109. Appeal of Denial of Application or Renewal. If an application or renewal is initially denied under this subchapter, the applicant or registrant may appeal such denial pursuant to the provisions of Chapter 1, Subchapter A of this title (relating to Rules of Practice and Procedure) and the Government Code, Chapter 2001.

§12.110. Regulatory Requirements Subsequent to Certification.

(a) The independent review organization shall report any material changes in the information required in the IRO Application Form, including changes relating to physicians and providers performing independent review, not later than the 30th day after the date on which the change takes effect.

(b) If the material change is a relocation of the organization:

(i) the organization must inform the department that the location is available for inspection by the department before the date of the relocation;

(ii) on request of the department, an officer shall attend the inspection; and

(iii) The inspection may include verification the IRO complies with the requirements in §12.103(11) of this subchapter (relating to Information required in Original Application for Certificate of Registration).

(c) Except as required in subsection (a) of this section, the independent review organization shall report any material changes in the information in the application required by §12.102 of this subchapter (relating to Independent Review Organization (IRO) Application Form) or renewal form required by §12.108 of this subchapter (relating to Renewal of Certificate of Registration) not later than the 30th day after the date on which the change takes effect.

(d) Compliance with subsection (a) of this section is exempted in the event that a contracted specialist is unavailable for review, and subsequent immediate contracting with a new specialist is necessary to complete independent review within the timeframes set forth in this chapter.

(e) The independent review organization shall notify the department within 10 days of any contracts entered into pursuant to subsection (d) of this section, and shall include in such notification a complete explanation of the circumstances necessitating such contracts.

§12.111. Effect of Sale of an Independent Review Organization.

(a) An independent review organization must notify the department of an agreement to transfer the ownership or sell the organization or shares in the organization not later than 60 days before the date of the sale or transfer of ownership. The notification must be filed with the department at the following address: Texas Department of Insurance, Mail Code 103-6A, P.O. Box 149104, Austin, Texas 78714-9104.

(1) The organization must submit the following information:

(A) name of the purchaser and a complete and legible set of fingerprints for each officer of the purchaser and for each owner or shareholder of the purchaser, or if the purchaser is publicly held, each owner or shareholder described by Insurance Code §4202.004(a)(1), and any additional information necessary to comply with Insurance Code §4202.004(d); and

(B) any material changes including, but not limited to policies and procedures, physical addresses, personnel, or operating locations with the notice of intent to sell. [~~Non-transferability of Certificate. An independent review organization's certificate is non-transferable, and an independent review organization must surrender its certificate upon sale of the independent review organization.~~]

(b) The IRO may complete the sale or transfer of ownership only after the department has sent written confirmation that the requirements under Insurance Code Chapter 4202 and this chapter have been satisfied. [~~Effect of Sale. An independent review organization that has been sold to a new owner must apply for and receive a~~

~~new certificate pursuant to this subchapter before it can operate as an independent review organization.]~~

(c) [~~Notification of Sale. An independent review organization must notify the department of an impending sale in writing at least 90 days prior to the date the sale will be finalized. The notification must include the date on which the sale is anticipated to be finalized, and the independent review organization must provide a revised notification of impending sale if the anticipated date for finalization of the sale changes. The notification must be filed with the Texas Department of Insurance at the following address: Texas Department of Insurance, Mail Code 103-6A, P.O. Box 149104, Austin, Texas 78714-9104.~~

~~(d)~~] Obligation to Continue Performing Duties Prior to Sale or Transfer of Ownership. An independent review organization must continue to perform all duties prior to the date that the sale or transfer of ownership of the independent review organization is finalized. [~~Independent reviews will not be assigned to the independent review organization during the 45 days prior to the date that the sale of the independent review organization is finalized.~~] Notification of the impending sale of an independent review organization does not negate the independent review organization's obligation to continue to perform its duties pursuant to the Insurance Code Chapters 1305 and 4202, the Labor Code Title 5, and applicable department and TDI-DWC rules.

[~~(e) Activities Following a Sale. Upon the sale of an independent review organization, the new owner is prohibited from performing the duties of an independent review organization specified in this chapter, the Insurance Code Chapters 1305 and 4202, the Labor Code Title 5, and applicable department and TDI-DWC rules prior to~~

~~issuance of the certificate of registration to the independent review organization pursuant to its new ownership.~~]

SUBCHAPTER C. GENERAL STANDARDS OF INDEPENDENT REVIEW

§12.201. Independent Review Plan. Independent review shall be conducted in accordance with an independent review plan that is consistent with standards developed with input from appropriate health care providers, and reviewed and approved by the IRO's medical director [~~a physician~~]. The independent review plan shall include the following components:

(1) A description of the elements of review which the independent review organization provides;

(2) written procedures for:

(A) notification of the independent review organization's determinations provided to the patient or a representative of the patient, the patient's provider of record, and the utilization review agent, in accordance with §12.206 of this subchapter (relating to Notice of Determinations Made by Independent Review Organizations);

(B) review, including:

(i) any form used during the review process;

(ii) timeframes that shall be met during the review;

(C) accessing appropriate specialty review;

(D) contacting and receiving information from health care providers in accordance with §12.205 of this subchapter (relating to Independent Review

Organization Contact with and Receipt of Information from Health Care Providers and Patients);

(3) required use of written medically acceptable review criteria that are:

(A) based on medical and scientific evidence and utilize evidence-based standards, or if evidence is not available, generally accepted standards of medical practice recognized in the medical community;

(B) established and periodically evaluated and updated with appropriate involvement from physicians, including practicing physicians, and other health care providers;

(C) objective, clinically valid, compatible with established principles of health care, and flexible enough to allow deviations from the norms when justified on a case-by-case basis;

(D) developed based on consideration of the treatment guidelines, treatment protocols, and pharmacy closed formulary as provided in orders issued or rules adopted by TDI-DWC, including Chapter 134 of this title (relating to Benefits--Guidelines for Medical Services, Charges, and Payments) and Chapter 137 of this title (relating to Disability Management) for health care provided pursuant to the Labor Code Title 5;

(E) used only as a tool in the review process; and

(F) available for review, inspection, and copying as necessary by the commissioner or the commissioner's designated representative in order for the commissioner to carry out the commissioner's lawful duties under the Insurance Code;

(4) independent review determinations that:

(A) utilize review procedures that are established and periodically evaluated and updated with appropriate involvement from physicians, including practicing physicians, and other health care providers;

(B) are made in accordance with medically accepted review criteria, taking into account the special circumstances of each case that may require a deviation from the norm; and

(C) are made by physicians, dentists, or other health care providers, as appropriate.

§12.202. Personnel and Credentialing.

(a) Personnel employed by or under contract with the independent review organization to perform independent review shall be appropriately trained and qualified and, if applicable, currently licensed, registered, or certified. Such personnel shall be currently involved in an active practice. An exception to the active practice requirement shall be the medical director of the independent review organization. Personnel who obtain information directly from a physician, dentist, or other health care provider, either orally or in writing, and who are not physicians or dentists, shall be nurses, physician assistants, or health care providers qualified to provide the service requested by the provider. This provision shall not be interpreted to require such qualifications for personnel who perform clerical or administrative tasks.

(1) Personnel conducting independent review for health services must hold an unrestricted license, an administrative license, or otherwise be authorized to provide health services by a licensing agency in the United States.

(2) Personnel conducting independent review for workers compensation healthcare services must hold an unrestricted license, an administrative license, or otherwise be authorized to provide workers compensation healthcare services by a licensing agency in this state.

(b) The independent review organization is required to provide to the commissioner:

(1) the name [~~number~~], type, and minimum qualifications of the personnel either employed or under contract to perform the independent review; and [~~.~~]

(2) [~~Independent review organizations are required to adopt~~] written procedures used to determine whether physicians or other health care providers utilized by the independent review organization are licensed, qualified, in good standing, and appropriately trained[~~, and maintain records on such. In addition, the independent review organization is required to maintain complete profiles of anyone conducting independent review. Such profiles are required to include all information required by the department in its application form and to be kept current and made available for review by the department and TDI-DWC upon request~~].

(c) An independent review organization shall be under the direction of a medical director who is a physician currently licensed and in good standing to practice medicine by a state licensing agency in the United States.

(d) The IRO must maintain credentialing files of the personnel either employed or under contract to perform the independent review. At a minimum, the IRO must keep the following credentialing information current and available for review by the department and TDI-DWC upon request:

(1) licensure, certification or registration , as applicable;

(2) active practice;

(3) board certification, if applicable; and

(4) any sanctions or revocations by any state licensing agency in the United States. [~~The independent review organization is required to provide to the department a copy of the applicant's credentialing policies and procedures, including:~~

~~(1) a description of the categories and qualifications of persons employed or under contract to perform independent review as described in this section;~~

~~(2) copies of policies and procedures for orientation and training of persons who perform independent review, and evidence that the applicant meets any applicable provisions of this chapter relating to the qualifications of independent review organizations or the performance of independent review.]~~

(e) Notwithstanding subsections (c) and (d) of this section, a physician, dentist, or other person who performs independent review whose license has been revoked by any state licensing agency in the United States is not eligible to direct or conduct independent review.

(f) Notwithstanding subsection (c) of this section, an independent review organization that performs independent review of a health care service provided under the Labor Code Title 5 or the Insurance Code Chapter 1305 shall comply with the licensing and professional specialty requirements for personnel performing independent review as provided by the Labor Code §§408.0043 - 408.0045 and 413.031; the Insurance Code §1305.355; and Chapters 133 and 180 of this title (relating to General Medical Provisions and Monitoring and Enforcement).

(g) The IRO must require the reviewer to sign and date the certification of independence and qualifications form prescribed by the commissioner prior to commencing the review.

(h) The information required in this section must be available for review by the department and TDI-DWC upon request.

(i)The reviewer must notify the IRO of any changes in the information in subsection (d) of this section.

§12.203. Conflicts of Interest Prohibited. A person that is a subsidiary of, or in any way owned or controlled by, a payor or trade or professional association of payors is not eligible for certification under this chapter. The department shall have the discretion to determine whether any other conflicts exist.

§12.204. Prohibitions of Certain Activities of Independent Review Organizations and Individuals or Entities Associated with Independent Review Organizations.

(a) An independent review organization shall not set or impose any notice or other review procedures that are contrary to the requirements of the health insurance policy or health benefit plan unless those requirements are set forth in this chapter or Texas law.

(b) An independent review organization may not permit or provide compensation or anything of value to its physicians or providers that would directly or indirectly affect an independent review decision.

(c) An independent review organization may not operate out of the same office or other facility as another independent review organization.

(1) This prohibition extends to the shared use by independent review organizations of the resources and staff that comprise an office, including: office space, telephone and fax lines, electronic equipment, supplies, and clerical staff.

(2) This prohibition does not extend to the use of subcontractor services or personnel employed by or under contract with the independent review organization to perform independent review.

(d) An individual who serves as an officer, director, manager, executive, supervisor, employee, agent, or independent contractor of an independent review organization may not serve as an officer, director, manager, executive, supervisor, employee, agent, or independent contractor of another independent review organization.

(e) An individual or an entity may not own more than one independent review organization.

(f) [~~(e)~~] An individual may not own stock in more than one independent review organization.

(g) [~~(f)~~] An individual may not serve on the board of more than one independent review organization.

(h) [~~(g)~~] An individual who has served on the board of an independent review organization that has had its certificate of registration revoked for cause may not serve on the board of another independent review organization earlier than the fifth anniversary of the date on which the revocation occurred.

(i) [~~(h)~~] Notwithstanding §12.4(b) of this chapter (relating to Applicability), the prohibitions in subsections (c) – (h) [~~(g)~~] of this section apply only to:

(1) an independent review organization that:

(A) is licensed on or after XX/XX/XXXX [~~December 26, 2010~~]; or

(B) has its certificate of registration renewed in this state on or after XX/XX/XXXX [~~December 26, 2010~~]; and

(2) an individual or entity whose activity involves an independent review organization that:

(A) is licensed on or after XX/XX/XXXX [~~December 26, 2010~~]; or

(B) has its certificate of registration renewed in this state on or after XX/XX/XXXX [~~December 26, 2010~~].

§12.205. Independent Review Organization Contact with and Receipt of Information from Health Care Providers and Patients.

(a) A health care provider may designate one or more individuals as the initial contact or contacts for independent review organizations seeking routine information or data. In no event shall the designation of such an individual or individuals preclude an independent review organization or medical director from contacting a health care provider or others in his or her employ where a review might otherwise be unreasonably delayed or where the designated individual is unable to provide the necessary information or data requested by the independent review organization.

(b) An independent review organization may not engage in unnecessary or unreasonably repetitive contacts with the health care provider or patient and shall base the frequency of contacts or reviews on the severity or complexity of the patient's condition or on necessary treatment and discharge planning activity.

(c) In addition to pertinent files containing medical and personal information, the utilization review agent or the health insurance carrier, health maintenance organization, managed care entity, or other payor requesting the independent review shall be responsible for timely delivering to and ensuring receipt by the independent review organization of any written narrative supplied by the patient pursuant to the Insurance Code Chapter 4201 and Chapters 19 and 133 of this title (relating to Agents' Licensing and General Medical Provisions). However, in instances of life-threatening condition, the independent review organization shall contact the patient or representative of the patient, and provider directly.

(d) An independent review organization shall notify the department if, within three working days of receipt of the independent review assignment, the independent review organization has not received the pertinent files containing medical and personal information from the requesting utilization review agent or the health insurance carrier, health maintenance organization, managed care entity, or other payor.

(e) An independent review organization shall reimburse health care providers for the reasonable costs of providing medical information in writing, including copying and transmitting any patient records or other documents requested by the independent review organization. A health care provider's charge for providing medical information to an independent review organization shall not exceed the cost of copying set by rules of TDI-DWC at §134.120 of this title (relating to Reimbursement for Medical Documentation) for records and may not include any costs that are otherwise recouped as a part of the charge for health care. Such expense shall be reimbursed by the utilization review agent, health insurance carrier, health maintenance organization,

managed care entity, or other payor requesting the review as an expense of independent review.

(f) Nothing in this section prohibits a patient, the representative of a patient, or a provider of record from submitting pertinent records to an independent review organization conducting independent review.

(g) When conducting independent review, the independent review organization shall request and maintain any information necessary to review the adverse determination not already provided by the utilization review agent, health insurance carrier, health maintenance organization, managed care entity, or other payor. This information may include identifying information about the patient, the benefit plan, the treating health care provider, or facilities rendering care. It may also include clinical information regarding the diagnoses of the patient and the medical history of the patient relevant to the diagnoses; the patient's prognosis; or the treatment plan prescribed by the treating health care provider along with the provider's justification for the treatment plan.

(h) The independent review organization is required to share all clinical and demographic information on individual patients among its various divisions to avoid duplication of requests for information from patients or providers.

§12.206. Notice of Determinations Made by Independent Review Organizations.

(a) An independent review organization shall notify the patient or a representative of the patient, the patient's provider of record, the utilization review agent, the payor, and the department of a determination made in an independent review.

(b) The notification required by this section must be mailed or otherwise transmitted not later than the earlier of:

(1) The 15th day after the date the independent review organization receives the information necessary to make a determination; or

(2) the 20th day after the date the independent review organization receives the request for the independent review.

(c) In the case of a life-threatening condition, the notification must be by telephone to be followed by facsimile, electronic mail, or other method of transmission not later than the earlier of:

(1) the 3rd [~~5th~~] day after the date the independent review organization receives the information necessary to make a determination; or with respect to:

(A) a review of a health care service provided to a person eligible for workers' compensation medical benefits,

[~~(2)~~] the 8th day after the date the independent review organization receives the request that the determination be made; or

(B) a review of health care service other than a service described by subparagraph (A), the 3rd day after the date the independent review organization receives the request that the determination be made [~~for independent review~~].

(d) Notification of determination by the independent review organization is required to include at a minimum:

(1) a listing of all recipients of the notification of determination as described in subsection (a) of this section, identifying for each:

(A) the name; and

(B) as applicable to the manner of transmission used to issue the notification of determination to the recipient:

(i) mailing address;

(ii) facsimile number; or

(iii) electronic mail address;

(2) the date of the original notice of the decision, and if amended for any reason, the date of the amended notification of decision;

(3) the independent review case number assigned by the department;

(4) the name of the patient;

(5) a statement of whether the type of coverage is health insurance, workers' compensation, or workers' compensation health care network;

(6) a statement of whether the context of the review is preauthorization, concurrent utilization review, or retrospective utilization review of health care services;

(7) the name and certificate number of the independent review organization;

(8) a description of the services in dispute;

(9) a complete list of the information provided to the independent review organization for review, including dates of service and document dates where applicable;

(10) a description of the qualifications of the reviewing physician or provider;

(11) a statement that the review was performed without bias for or against any party to the dispute and that the reviewing physician or provider has certified that no known conflicts of interest exist between the reviewer and:

(A) the patient;

(B) the patient's employer, if applicable;

(C) the insurer;

(D) the utilization review agent;

(E) any of the treating physicians or providers; or

(F) any of the physicians or providers who reviewed the case for determination prior to referral to the independent review organization, and that the review was performed without bias for or against any party to the dispute;

(12) a statement that the independent review was performed by a health care provider licensed to practice in Texas if required by applicable law and of the appropriate professional specialty;

(13) a statement that there is no known conflict of interest between the reviewer, the IRO, and/or any officer or employee of the IRO with:

(A) the patient;

(B) the provider requesting independent review;

(C) the provider of record;

(D) the utilization review agent;

(E) the payor; and

(F) the certified workers' compensation health care network, if applicable;

(14) a summary of the patient's clinical history;

(15) the review outcome, clearly stating whether or not medical necessity or appropriateness exists for each of the health care services in dispute and whether the health care services in dispute are experimental or investigational, as applicable;

(16) a determination of the prevailing party if applicable;

(17) the analysis and explanation of the decision, including the clinical bases, findings and conclusions used to support the decision;

(18) a description and the source of the review criteria that were utilized to make the determination;

(19) a certification by the independent review organization of the date that the decision was sent to all of the recipients of the notification of determination as required in subsection (a) of this section via U.S. Postal Service or otherwise transmitted in the manner indicated on the form; and

(20) for independent reviews of health care services provided under the Labor Code Title 5 or the Insurance Code Chapter 1305, any information required by §133.308 of this title (relating to MDR by Independent Review Organizations); and

(21) notice of applicable appeal rights under the Insurance Code Chapter 1305 and the Labor Code Title 5, and instructions concerning requesting such appeal.

(e) Example templates for the notification of determination regarding health and workers' compensation cases may be found on the department's website at http://tdi.texas.gov/forms [~~http://www.tdi.state.tx.us/forms~~].

§12.207. Independent Review Organization Telephone Access.

(a) An independent review organization shall have appropriate personnel reasonably available by telephone at least 40 hours per week during normal business hours in both time zones in Texas.

(b) An independent review organization must have a telephone system capable of accepting or recording or providing instructions to incoming calls related to utilization review during other than normal business hours and shall respond to such calls not later than one working day from the date the call was received.

§12.208. Confidentiality.

(a) An independent review organization shall preserve the confidentiality of individual medical records, personal information, and any proprietary information provided by payors. Personal information shall include, at a minimum, name, address, telephone number, social security number and financial information.

(b) An independent review organization is prohibited from publicly disclosing patient information protected by the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. Section 1320d et seq.) or transmitting the information to a subcontractor involved in the independent review process that has not signed an agreement similar to the business associate agreement required by regulations adopted under the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. Section 1320d et seq.).

(c) An independent review organization may not disclose or publish individual medical records or other confidential information about a patient without the prior written consent of the patient or as otherwise provided by law, including the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. Section 1320d et seq.), if

applicable. An independent review organization may provide confidential information to a provider who is under contract with the independent review organization for the sole purpose of performing or assisting with independent review. Information provided to a provider who is under contract to perform a review shall remain confidential.

(d) [~~(c)~~] The independent review organization may not publish data which identify a particular payor, physician or provider, including any quality review studies or performance tracking data, without prior written consent of the involved payor, physician or provider. This prohibition does not apply to internal systems or reports used by the independent review organization.

(e) [~~(d)~~] All payor, patient, physician, and provider data shall be maintained by the independent review organization in a confidential manner which prevents unauthorized disclosure to third parties. Nothing in this chapter shall be construed to allow an independent review organization to take actions that violate a state or federal statute or regulation concerning confidentiality of patient records.

(f) [~~(e)~~] To assure confidentiality, an independent review organization must, when contacting a utilization review agent, a physician's or provider's office, or hospital, provide its certificate number and the caller's name and professional qualifications to the provider or the provider's named independent review representative.

(g) [~~(f)~~]The independent review organization's procedures shall specify that specific information exchanged for the purpose of conducting review will be considered confidential, be used by the independent review organization solely for the purposes of independent review, and be shared by the independent review organization with only a provider who is under contract with the independent review organization to perform

independent review. The independent review organization's plan shall specify the procedures that are in place to assure confidentiality and shall acknowledge that the independent review organization agrees to abide by any federal and state laws governing the issue of confidentiality. Summary data that does not provide sufficient information to allow identification of individual patients, providers, payors or utilization review agents need not be considered confidential.

(h) [~~(g)~~] Medical records and patient-specific information shall be maintained by the independent review organization in a secure area with access limited to essential personnel only. Independent review organizations must transmit and store records in compliance with the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. Section 1320d et seq.).

(i) [~~(h)~~] Information generated and obtained by the independent review organization in the course of the review shall be retained for at least four years. This requirement is not negated by the suspension or surrender of the independent review organization's certificate of registration or the failure to renew the certificate of registration.

(j) [~~(i)~~] Destruction of documents in the custody of the independent review organization that contain confidential patient information or payor, physician or provider financial data shall be by a method which ensures complete destruction of the information, when the organization determines that the information is no longer needed.

SUBCHAPTER D. ENFORCEMENT OF INDEPENDENT REVIEW STANDARDS

§12.301. Complaints, Oversight, and Information.

(a) Complaints against an independent review organization shall be processed in accordance with the department's established procedures for investigation and resolution of complaints.

(b) As part of its oversight of independent review organizations, the department will conduct compliance audits to ensure that independent review organizations are in compliance with the Insurance Code Chapters 1305 and 4202 and the rules and standards in this chapter.

(c) The department may use the authority of the Insurance Code §38.001 to make inquiries of any independent review organization.

(d) This chapter does not limit the ability of the Commissioner of Workers' Compensation or TDI-DWC to make inquiries, conduct audits, or receive and investigate complaints against independent review organizations or personnel employed by or under contract with independent review organizations to perform independent review to determine compliance with or violations of the Labor Code Title 5 or applicable TDI-DWC rules.

§12.302. Administrative Violations.

(a) If the department believes that any person conducting independent review is in violation of the Insurance Code Chapters 1305 or 4202 or this chapter, or any provision of the Labor Code Chapters 408, 409, or 413, or Chapters 19, 133, 134, 140, or 180 of this title (relating to Agents' Licensing; General Medical Provisions; Benefits--Guidelines for Medical Services, Charges, and Payments; Dispute Resolution--General Provisions and Monitoring and Enforcement), respectively, the department shall notify the independent review organization of the alleged violation and may compel the

production of any and all documents or other information as necessary to determine whether or not such violation has taken place.

(b) The department or TDI-DWC may initiate appropriate proceedings under this chapter or the Labor Code Title 5 and TDI-DWC rules.

(c) Proceedings under this chapter are a contested case for the purpose of the Government Code, Chapter 2001.

(d) If the commissioner or the commissioner's designee determines that an independent review organization or a person conducting independent review has violated or is violating any provision of the Insurance Code Chapter 4202 or this chapter, the commissioner or the commissioner's designee may:

(1) impose sanctions under the Insurance Code Chapter 82;

(2) issue a cease and desist order under the Insurance Code Chapter 83; and/or

(3) assess administrative penalties under the Insurance Code Chapter 84.

(e) If the independent review organization has violated or is violating any provisions of the Insurance Code other than Chapter 4202, or applicable rules of the department, sanctions may be imposed under the Insurance Code Chapters 82, 83, or 84.

(f) The commission of fraudulent or deceptive acts or omissions in obtaining, attempting to obtain, or use of certification or designation as an independent organization shall be a violation of the Insurance Code Chapter 4202.

(g) If the commissioner or the commissioner's designee determines that an independent review organization or a person conducting independent review has

violated or is violating any provision of the Labor Code Title 5 or rules adopted pursuant to the Labor Code Title 5, the commissioner or the commissioner's designee may impose sanctions or penalties under the Labor Code Title 5.

(h) This chapter does not limit the ability of the Commissioner of Workers' Compensation or TDI-DWC to make inquiries, conduct audits, receive and investigate complaints, and take all actions permitted by the Labor Code against an independent review organization or personnel employed by or under contract with an independent review organization to perform independent review to determine compliance with the Labor Code Title 5 and applicable TDI-DWC rules.

§12.303. Surrender of Certificate of Registration.

(a) Pursuant to the Insurance Code §4202.002(c)(2)(B), upon the request of the department, an independent review organization must surrender the organization's certificate of registration [~~while the organization is under investigation or~~] as part of an agreed order.

(b)[~~For the purposes of this section, the term "investigation" is defined as the filing of a Notice of Hearing or a Notice of Violation with the State Office of Administrative Hearings by the department or TDI-DWC against an independent review organization where such notice seeks revocation of the certificate of registration of the independent review organization.~~

~~(c) A certificate of registration that is surrendered under this section is temporarily suspended while the investigation is pending.~~

~~(d)~~] Independent reviews shall not be assigned to an independent review organization during a surrender of the independent review organization's certificate of registration.

(c) [~~(e)~~] Surrender of an independent review organization's certificate of registration does not negate the requirement in §12.208(i) [~~(h)~~] of this chapter (relating to Confidentiality) that an independent review organization retain information generated and obtained by the independent review organization in the course of a review for at least four years or the obligation to complete all independent reviews assigned to the independent review organization prior to the surrender of the certificate of registration.

[~~(f) Notwithstanding §12.4(b) of this chapter (relating to Applicability), this section only applies to an independent review organization that:~~

~~(1) is licensed on or after December 26, 2010; or~~

~~(2) has its certificate of registration renewed in this state on or after December 26, 2010.~~]

SUBCHAPTER E. FEES AND PAYMENT

§12.401. Fees.

(a) The commissioner shall establish, administer, and enforce the certification and renewal fees under this section in amounts not greater than necessary to cover the cost of administration of this chapter.

(b) Fees for independent review shall be determined by the department, and shall reflect in general the market value of services rendered.

§12.402. Classification of Specialty. Fees for independent review shall be based on a two tiered structure of specialty classifications as follows:

(1) Tier one fees will be for independent review of medical or surgical care rendered by a doctor of medicine or doctor of osteopathy.

(2) Tier two fees will be for the independent review of health care services rendered in the specialties of podiatry, optometry, dental, audiology, speech-language pathology, master social work, dietetics, professional counseling, psychology, occupational therapy, physical therapy, marriage and family therapy, chiropractic, and chemical dependency counseling, and any subspecialties thereof.

§12.403. Fee Amounts.

(a) Fees to be paid to independent review organizations by utilization review agents, and other payors, for each independent review are as follows:

(1) tier one: $650; and

(2) tier two: $460.

(b) The IRO fees specified in subsection (a) of this section include an amended notification of decision if the department determines the initial notification of decision is incomplete. The amended notification of decision shall be filed with the department no later than five working days from the independent review organization's receipt of notice from the department that the initial notification of decision is incomplete.

§12.404. Payment of Fees.

(a) Independent review organizations shall bill utilization review agents or payors, as appropriate, directly for fees for independent review.

(b) Independent review organizations may also bill utilization review agents or payors, as appropriate, for copy expenses related to review as set forth in §12.205 of

this chapter (relating to Independent Review Organization Contact with and Receipt of Information from Heath Care Providers and Patients).

(c) Utilization review agents or payors, as appropriate, shall pay independent review organizations directly within 30 days of receipt of invoice. For workers' compensation network and non-network disputes, the independent review organization fees shall be paid in accordance with §133.308 of this title (relating to MDR by Independent Review Organizations).

(d) Utilization review agents may recover from the payors the costs associated with the independent review.

§12.405. Failure To Pay Invoice. Failure by utilization review agents or payors, as appropriate, to pay invoices from an independent review organization within 30 days of receipt shall constitute a violation of §12.404(c) of this subchapter (relating to Payment of Fees) and shall be subject to enforcement action and penalty in accordance with §12.302 of this chapter (relating to Administrative Violations).

§12.406. Certification and Renewal Fees. The fee [~~Fees~~] to be paid to the department for the original application for a certificate of registration as an independent review organization is $1000 [~~$800~~]. The fee for renewal of a certificate of registration is $400 [~~$200~~].

SUBCHAPTER F. RANDOM ASSIGNMENT OF INDEPENDENT REVIEW ORGANIZATIONS

§12.501. Requests for Independent Review. Requests for independent review shall be made to the department on behalf of the patient by the utilization review agent pursuant to the Insurance Code Chapter 4201, Subchapter I and Chapter 19, Subchapters R and

U of this title (relating to Utilization Review Agents), Chapter 10 of this title (relating to Workers' Compensation Health Care Networks), Chapter 133 of this title (relating to General Medical Provisions), Chapter 134 of this title (relating to Benefits – Guidelines for Medical Services, Charges, and Payments), or by a health insurance carrier, health maintenance organization, or managed care entity pursuant to the Civil Practice and Remedies Code §88.003(c).

§12.502. Random Assignment.

(a) The department shall randomly assign each request for independent review to an independent review organization and shall notify the utilization review agent and the health insurance carrier, health maintenance organization, managed care entity, or other payor requesting the independent review, the independent review organization, the patient or a representative of the patient, and the provider of record of such assignment.

(b) The department shall screen payors and utilization review agents for potential conflicts of interest with the independent review organization before making an assignment to the independent review organization. The independent review organization shall screen its physicians and other providers conducting independent review for potential conflicts of interest. The department shall have the discretion to determine whether conflicts exist.

(c) Independent review organizations shall be added to the list from which random assignments for independent review are made in order of the date of issuance of the certificate of registration by the department.

(d) Random assignment shall be made chronologically from the list of independent review organizations with ultimate assignment to the first in line with no apparent conflicts of interest.

(e) Assignment of an independent review to an independent review organization moves the independent review organization receiving the assignment to the bottom of the assignment list.

(f) Independent reviews will not be assigned:

(1) to an independent review organization during the 30 days prior to the anniversary date of the issuance of the independent review organization's certificate of registration unless the completed application for renewal of its certificate of registration and the application fee have been received by the department; or

(2) during the time that an independent review organization has surrendered its certificate of registration pursuant to §12.303 of this chapter (relating to Surrender of Certificate of Registration) and the Insurance Code §4202.002(c)(2)(B).

(g) Nonselection for presence of conflicts of interest does not move the independent review organization to the bottom of the assignment list. Such independent review organization retains its chronological position until selected for independent review.